

REMARKS

Claims 1-18 were pending. Claims 7, 9, 16 and 18 have been withdrawn from consideration. Claims 2 and 14 are canceled. Claims 1, 3 and 10 have been amended. No new matter is added. Applicants respectfully request reconsideration of the rejections.

Support for the amending language "lower intestinal tract" may be found in the specification at paragraph 4, line 5. Support for the amending language "hinged" and "two or more jaw elements" with respect to the grasping member, may be found in the specification at paragraph 27, line 4.

Claim 1-6, 8, 10-15 and 17 have been rejected under 35 U.S.C. 103(a) as unpatentable over Giantureo *et al.*, U.S. Patent no. 6,187,116, in view of Hedges *et al.*, U.S. Patent no. 5,035,706. The Office Action states that Giantureo discloses a luminal stent wherein the drawstring is slack during normal use and is tightened for compressing and removing the stent from the body lumen. It is stated that Hedges *et al.* teaches a stent removal device comprising a flexible elongate member for actuating the grasping member that allows the artery to remain expanded and enables the stent to be readily withdrawn from its location in the lumen.

Applicants respectfully submit that the presently claimed invention is not taught or suggested by the cited combination of art. Applicants claim a method of removing or repositioning a stent from the lower gastrointestinal tract; and a system for accomplishing the removal or repositioning.

In the presently claimed methods of the invention, the grasping member of a stent removal device is used to tighten a drawstring of a stent. The grasping element, as shown in Figure 2, comprises two or more jaws, that are hinged at the juncture with the flexible elongated member. Such a device is tailored to pulling the drawstring taut. The elongated member of the stent removal device contains elements for controlling the grasping member. However, this elongated member is not suitable for withdrawing the stent. As shown in Figure 5B, in order to withdraw the stent without damage to the surrounding tissue, it is preferable that the stent removal device comprise a protective sheath. During introduction of the distal end of the device that includes the grasping members into the body during use, the grasping members or fingers may be retracted into the protective housing to aid in placement of the device at the location of the stent. After the distal end of the device has been positioned at the location of the object to be manipulated, the grasping members may be protruded from the protective housing. Certain flexible stents can be withdrawn into the protective sheath, by grasping the drawstring to reduce the diameter, and withdrawing the grasping member and stent together into the sheath.

The stent removal system described by Hedges *et al.* differs in design and purpose from the removal system of the present invention. Hedges *et al.* teaches flexible fingers which curve around the entire stent to pull it out. The flexible fingers are not hinged, as recited in independent Claim 10 of the present application. As the Hedges *et al.* fingers are flexible, hinges are not a useful element and would interfere with the withdrawal of the stent. Because the Hedges *et al.* device surrounds the stent, enclosing it within the flexible fingers, hinges would be a barrier to the function of the device.

Further, as shown in Figure 1 of US 6,187,016; the Hedges *et al.* fingers enclose the stent, and withdraws the stent thus enclosed. In contrast, because Applicants are using the grasping members pull the drawstring and decrease the diameter of the stent, not to enclose it, Applicants device comprises an additional protective sheath element, as recited in Claims 1 and 11. The stent is withdrawn into the protective sheath, not within the grasping element jaws.

Applicants respectfully submit that the presently claimed method and device are not taught or suggested by the cited combination of prior art. Hedges *et al.* fails to teach a stent removal device comprising hinged grasping members; and fails to teach the inclusion or importance of an additional protective sheath into which a stent can be withdrawn.

The methods taught by Hedges *et al.* differ from those of the present invention, because the prior art encloses a stent within flexible fingers, and do not use a grasping element to tighten a drawstring and withdraw a stent into a protective sheath.

The secondary reference, Giantureo *et al.*, fails to remedy the deficiencies of the primary reference. Giantureo *et al.* teach a stent with tightening drawstring, but fails to teach or suggest a stent removal device with grasping members. Based on the drawings (see Figure 8) provided by Giantureo *et al.*, the drawstring seems to be led directly through an elongated member. As Giantureo *et al.* is directed to the use of percutaneous stents, such a method can be used. However, for Applicants methods relating to gastrointestinal stents, the distance between the position of the stent and the actuating mechanism may be considerable. Further, the methods of the invention provide for means of removing stents that have been in position for a period of time, as lower gastrointestinal stents usually become obstructed with time. The positioning system depicted by Giantureo *et al.* would not be useful in these circumstances.

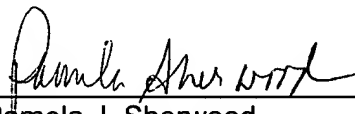
In view of the above amendments and remarks, Applicants respectfully submit that the presently claimed invention is not made obvious by the cited references of Giantureo *et al.* and Hedges *et al.* Withdrawal of the rejection is requested.

Applicant submits that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number STAN-219.

Respectfully submitted,
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